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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,057	09/14/2005	James Hill	41577/312173	5838

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,057	HILL ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-32* is/are pending in the application.

4a) Of the above claim(s) *25-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and remarks, filed on 12/12/2007, are acknowledged. Claims 17, 24, and 32 are amended. Claims 17-32 are pending. Claims 25-32 are withdrawn as being drawn to nonelected inventions. Claims 17-24 are currently under examination.

Objections Withdrawn

The objection to the specification the sequence of the V-antigen is deemed to be essential matter, is withdrawn in light of applicant's amendment thereto.

The objection to claims 17-21 and 23-24 because the claims are drawn, in part, to nonelected subject matter, is withdrawn in light of applicant's amendment thereto.

Claim Rejections Withdrawn

The rejection of claims 17-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn. Applicant's arguments have been fully considered and are persuasive.

The rejection of claims 17-24 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling (after perfecting the deposit requirements for the hybridomas to produce the monoclonal antibodies, as discussed in the rejection below) for methods of treating a human or animal suffering from the effects of infection with *Yersinia pestis*, comprising administering to the human or animal, a therapeutically effective amount of a medicament comprising the monoclonal antibodies, Mab F1-04-A-G1 and Mab 7.3, does not reasonably provide enablement for the methods as claimed, is withdrawn. Applicant's arguments have been fully considered and are persuasive.

The rejection of claims 17-24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (biological deposit rejection), is withdrawn. Applicant's arguments have been fully considered and are persuasive.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "amino acids 135-275 of the sequence of the V-antigen," is withdrawn in light of applicant's amendment to the specification.

The rejection of claim 23 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "amino acids 1-275 of the sequence of the V-antigen," is withdrawn in light of applicant's amendment to the specification.

The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "parental administration," is withdrawn in light of applicant's amendment thereto.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill *et al.* (Infect. Immun., 65:4476-4482, 1997; IDS filed 7/19/2005) in view of Anderson *et al.* (Am. J. Trop. Med. Hyg., 56:471-473, 1997; IDS filed 7/19/2005) and Casadevall (Clin. Immunol., 93:5-15, 1999; IDS filed 7/19/2005).

The instant claims are drawn to treatment methods for a human or animal suffering from the effects of *Yersinia pestis* infection, comprising administering an antibody specific for *Yersinia pestis* F1-antigen and an antibody specific for *Yersinia pestis* V-antigen (claim 17);

wherein the antibodies are monoclonal antibodies (claim 18); wherein the medicament is for administration up to about 48 hours post-infection (claim 19); wherein the antibody specific for Yersinia pestis V-antigen or binding fragment thereof specifically binds an epitope of the V-antigen found between amino acids 135-275 of the sequence of the V-antigen (claim 20); wherein the antibodies, or binding fragments thereof, are humanised (claim 21); wherein the method comprises administering a combination of an antibody specific for Yersinia pestis F1-antigen and an antibody specific for Yersinia pestis V-antigen (claim 22); wherein the antibody specific for Yersinia pestis V-antigen or binding fragment thereof specifically binds an epitope of the V-antigen found between amino acids 1-275 of the sequence of the V-antigen (claim 23); wherein the medicament is administered in a form suitable for oral use, for administration by inhalation, for administration by insufflation or for parenteral administration (claim 24).

Hill *et al.* disclose a method of protecting an animal from *Yersinia pestis* infection by administering monoclonal antibody 7.3, which binds to an epitope between amino acids 135-275 of *Yersinia pestis* V-antigen (see abstract and page 4479, column 2, paragraphs 5-6). The antibodies were administered intraperitoneally (see page 4477, column 2, 4). Hill *et al.* also discloses that a subunit vaccine containing the F1 and V-antigens was shown to protect mice against infection by *Yersinia pestis* at a higher level than either subunit alone (see page 4476, column 2, paragraph 1).

Hill *et al.* differs from the instant invention in that antibodies against the *Yersinia pestis* F1-antigen are not used, and the antibodies are administered to a subject before infection occurs, rather than after infection occurs. In addition, the antibodies are not disclosed as being humanised.

Anderson *et al.* disclose a method of protecting an animal from *Yersinia pestis* infection by administering monoclonal antibody F1-04-A-G1, which is specific for the *Yersinia pestis* F1-antigen, prior to infection with *Yersinia pestis* (see abstract and Table 1).

Casadevall provides a review of passive antibody therapies and discloses that passive immunization as a therapy for disease has been in use for many diseases since as far back as the 1890's (see Introduction). Additionally, Casadevall discloses that one of the disadvantages of passive immunotherapy is that use of antibodies from other species leads to toxicity in humans. This can be overcome by using humanized antibodies (see Figure 1).

Therefore, it would have been obvious, to one of ordinary skill in the art, at the time of invention, to combine antibodies against *Yersinia pestis* F1-antigen with antibodies against *Yersinia pestis* V-antigen to use in a method of treating a subject with a *Yersinia pestis* infection because passive immunotherapy has been widely used for many years against many types of infection and because vaccination with a subunit vaccine containing both the F1 and V-antigen has been shown to protect at a higher level than either subunit alone. It would also have been obvious to use humanized antibodies to avoid the toxic effects of heterologous antibodies.

One would have had a reasonable expectation of success because passive immunotherapy has been used in treatment of other infections and because "humanizing" antibodies is a widely known and used method. Therefore, in the absence of any evidence of unexpected results, one would have expected passive immunotherapy treatment to be effective in treatment of *Yersinia pestis* infection.

With regard to claim 19, it is noted that there is no method step requiring administration of the antibodies within 48 hours; the claim simply states that the medicament is for administration up to 48 hours post-infection.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Shanon A. Foley/
Supervisory Patent Examiner, Art Unit 1645